K062952 (p. 1 of 3)

Sec. 5
510(k) Summary
LMT nomag IC 3.0

JUL 31 2006

Preparation Date:	Feb, 17th 2006
Applicant	LMT Lammers Medical Technology GmbH Osterweide 8 23568 Luebeck Germany
Establishment Registration No.	3004083324
Contact Person:	Thomas Michael Bohnen Tel: +49-451-58098-0 Fax. +49-451-58098-15 Email: bohnen@lammersmedical.com
Common Device Name	Neonatal Transport Incubator
Device Panel:	General Hospital
Product Code Regulation No.	FPL (Incubator, Neonatal Transport) 880.5410
Class	2
Propietary Name REF:	LMT nomag IC 3.0 LMT-0100004-A
Performance Standard:	IEC 60601-2-20: 1996 IEC 60601-1 (Ed.2): 1995 ISO 10993: 1997
Legally marketed device	LMT nomag IC 1.5 K#033565
Reason for 510(k):	extended indications for use

K062952 (p.2 of 3)

Sec. 5
510(k) Summary
LMT nomag IC 3.0

LMT

Intended Use of the LMT nomag IC 3.0

The LMT nomag IC 3.0 is an infant incubator system for temporary use during MR-imaging in clinical environments and provided with a suitable trolley for intra hospital transport.

The LMT nomag IC 3.0 MR-incubator provides a controlled environment of warmth and humidity for premature babies and sick infants up to a body weight of 4.5 kg (10 lbs) and a maximum body length of 55 cm (21.7 inches).

The LMT nomag IC 3.0 is suitable for use with MR scanners of field strengths up to 3.0T.

Function of the Device

The LMT Nomag IC 3.0 is an incubator for preterm and term-born infants who are scheduled for Magnetic Resonance (MR) Imaging and are dependant on warming therapy. It provides a microclimate of air temperature and humidity suiting the infants needs. The incubator has a trolley for intra clinical transport providing power.
The incubator runs in air control mode and has closed loop control for both air temperature and humidity. Humidification works hygienically via vaporizing of distilled water.

Design and Specifications
The basic incubator performance of the LMT nomag IC 3.0 is defined by the IEC particular standard and the design changes over the nomag IC 1.5. do not affect these performance figures.

Testing under MR influence
The compatibility to MR scanners with 3T field strength has been proven in extensive bench testing.

Image evaluation was performed to the same standards as with the nomag IC 1.5.

K962952 (p3of3)

Sec. 5
510(k) Summary
LMT nomag IC 3.0

The compatibility with MR scanners of different manufacturers (Siemens, Philips, GE 1.5T and 3T) have been tested according to an established protocol using phantoms.
During this testing the behaviour of the incubator has shown no adverse effects in neither direction. The incubator performance was not influenced in any way by the scanner and the imaging has not shown significant artefacts caused by the incubator. Other functions of the scanner were also not influenced by the incubator.

SE Statement

The LMT Nomag IC 3.0 incubator is substantially equivalent to the legally marketed device. It is compliant with international harmonized standards for incubators by the IEC.
The testing did not rise new risks or questions associated with the use of a MR compatible incubator.

The LMT Nomag IC 3.0 works as safe and effective as the legally marketed device.

T. M. Bohnen

.....
Thomas Michael Bohnen
RA
LMT Lammers Medical Technology GmbH, Germany

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2006

LMT Lammers Medical Technology GmbH
C/O Mr. Jeffrey D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K062052
Trade/Device Name: LMT Nomag IC 3.0
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: June 19, 2006
Received: July 20, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062052

Device Name: LMT nomag IC 3.0

Indications for Use:

The LMT nomag IC 3.0 MR-incubator is an infant incubator system for temporary use during MR-imaging in clinical environments provided with à suitable trolley for intra hospital transport.

The LMT nomag IC 3.0 MR-incubator provides a controlled environment of warmth and humidity for premature babies and sick infants up to a body weight of 4.5 kg (10 lbs) and a maximum body length of 55 cm (21.7 inches).

The LMT nomag IC 3.0 is suitable for use with MR scanners of field strengths up to 3.0T.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...gn Off)
...of Anesthesiology, General Hospital
...on Control, Dental Devices
...umber K062052